

## **REMARKS**

This response is supplemental to the response to non-final Office Action filed January 14, 2004. Following entry of the amendment presented in the response January 14, 2004, Claims 112-131 will be pending and under consideration.

In the response filed January 14, 2004, Applicants requested that the provisional obviousness-type double patenting rejection of Claims 112-114 over Claims 1, 2, 5, and 6 of co-pending U.S. Application No. 10/139,069 ("the '069 application") be removed pursuant to M.P.E.P. § 804 I.B. and be made non-provisionally in connection with the claims of the '069 application. Applicants have reconsidered this request and instead prefer to address the provisional obviousness-type double patenting rejection in connection with the claims of the present application, as set forth below.

### **I. The Provisional Rejection of Claims 112-114 under the Judicially-Created Doctrine of Obviousness-Type Double Patenting**

Claims 112-114 stand provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over Claims 1, 2, 5, and 6 of the '069 application. Applicants respectfully submit that the rejection of Claims 112-114 on this basis is in error because none of the rejected claims is an obvious variant of any claim of the '069 application.

#### **A. The Legal Standard**

Under the judicially-created doctrine of obviousness-type double patenting, a claim must be patentably distinct from a claim of an already issued patent or pending application. *See General Food Corp. v. Studiengesellschaft Kohle mbH*, 23 U.S.P.Q.2d 1839 (Fed. Cir. 1992). If the claim at issue defines more than an obvious variation of the patented or pending claim, it is patentably distinct and rejection of the claim under the doctrine of obviousness-type double patenting is improper. *See id.* To establish a proper obviousness-type double patenting rejection, the Examiner must show that the claim at issue is a "mere variation" of the patented or pending claim that "would have been obvious to those of ordinary skill in the relevant art." *See In re Kaplan*, 229 U.S.P.Q. 678, 683 (Fed. Cir., 1986). Finally, where the claim at issue is alleged to be an obvious variant of a currently pending claim, a rejection on these grounds is provisional. *See M.P.E.P. § 804 I.B.* If such a provisional rejection is the last remaining issue preventing passage of the rejected claim to issuance, the rejection should be removed and the claim in the other pending application should be non-provisionally rejected. *See id.*

**B. Claims 112-114 are not Obvious Variants of any Claim of the '069 Application**

Claims 112-114 are directed to methods for determining susceptibility of a hepatitis C ("HCV") viral population infecting a patient to an antiviral drug. In contrast, the presently-pending claims of the '069 application are directed to methods for determining whether an HCV has an altered susceptibility to an anti-HCV compound relative to a reference HCV, whether a compound affects an HCV, and whether a patient infected with an HCV is likely to be susceptible to treatment with an anti-HCV compound. For the PTO's convenience, a copy of the claims presently pending in the '069 application is attached hereto as Exhibit A.

No *claim* of the '069 application suggests that the methods claimed therein could or should be adapted to assess the susceptibility of HCV viral populations infecting a patient to an anti-viral drug as recited by, for example, Claims 112 and 116 of the present application, rather than a single HCV. The PTO is respectfully reminded that the doctrine of obviousness-type double patenting requires a comparison of claims, not a comparison of disclosures. *See* M.P.E.P. § 804 III. Since no claim of the '069 application suggests methods for assessing the susceptibility of HCV populations infecting a patient to an HCV anti-viral drug, no claim presently pending in the instant application is an obvious variant of any claim of the '069 application.

In view of the foregoing, Applicants respectfully submit that Claims 112-114 are not obvious variants of any presently-pending claim of the '069 application. Accordingly, Applicants respectfully suggest that the provisional rejection of Claims 112-114 under the judicially-created doctrine of obviousness-type double patenting is in error, and earnestly request its withdrawal.

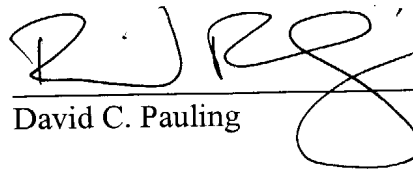
## CONCLUSION

In light of the above amendments and remarks, Applicants respectfully submit that Claims 112-131 satisfy all the criteria for patentability and are in condition for allowance. Accordingly, Applicants respectfully request that the Examiner reconsider this application with a view towards allowance and solicit an expeditious passage of Claims 112-131 to issuance.

Applicants believe that no fee is due in connection with this response. Nonetheless, pursuant to 37 CFR § 1.136(a)(3), the Commissioner is authorized to charge all required fees, fees under 37 CFR § 1.17 and all required extension of time fees, or credit any overpayment, to Jones Day U.S. Deposit Account No. 503 013 (order no. 101962-999043).

Respectfully submitted,

Date: June 3, 2004



David C. Pauling

P56,056  
(Reg. No.)

For: Nikolaos C. George (Reg. No. 39,201)

**JONES DAY**

222 East 41st Street

New York, N.Y. 10017-6702

(212) 790-9090